REMARKS

Claims 3, 6 and 9-40 are pending in this application, with claims 3, 6, 9-31, 34, 37 and 38 withdrawn from consideration. Claims 33, 35, 36, 39 and 40 are canceled without prejudice or disclaimer, and claim 32 is amended herein. Upon entry of this amendment, claims 3, 6, 9-32, 34, 37 and 38 will be pending, with claims 3, 6, 9-31, 34, 37 and 38 withdrawn from consideration. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is discussed below.

Claims 32-33, 35-36 and 39-40 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office action paragraph no. 5)

The rejection of claims 33, 35, 36, 39 and 40 is moot in view of the cancellation of these claims without prejudice or disclaimer. The rejection of claim 32 is overcome by the amendment to the claim.

The Examiner states that the terms "Df allergens" and "Pfu protease S" are indefinite.

Claim 32 has been amended to the term "dust mite extract-Df" with "*Dermatophagoides farinae* Hughes." Support for this amendment may be found in the attached document "Mite Extract-Df," which demonstrates that an extract of the dust mite *Dermatophagoides farinae* Hughes is known in the art.

Claim 32 has also been amended to clarify the recitation of "enzyme," by reciting: "wherein the enzyme is an enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene, or papain." Support for the recitation regarding the *Pyrococcus furiosus* protease gene may be found in canceled claim 39, and in the attached document "*Pfu* Protease S." Support for the recitation regarding papain may be found, for example, in claim 31.

Claims 32-33, 35-36 and 39-40 are rejected under 35 U.S.C. §112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. (Office action paragraph no. 7)

Claims 32-33, 35-36 and 39-40 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. (Office action paragraph no. 8)

The rejection of claims 33, 35, 36, 39 and 40 is moot in view of the cancellation of these claims without prejudice or disclaimer. The rejection of claim 32 is overcome by the amendment to the claim.

In Office action paragraph no. 7, the Examiner states that the claims are enabling for "an allergen inactivating method for dust mite extract-Df allergens by maintaining the dust mist extract Df-allergens under a condition in which Pfu protease S or papain enzymes and urea or SDS exist." Claim 32 has been amended to require "an enzyme of *Bacillus* species carrying a plasmid that

encodes the *Pyrococcus furiosus* protease gene, or papain" and to require sodium dodecylsulfate (SDS) or urea.

In Office action paragraph no. 8, the Examiner states that Applicant is in possession of: "an allergen inactivating method for dust mite extract-Df allergens by maintaining the allergens under a condition in which Pfu protease S or papain enzymes and SDS or urea exist." The issue appears to be related to that in paragraph no. 7 of the Office action, and Applicant submits that claim 32 has been amended to be limited in this manner.

Claims 32-33 and 35-36 are rejected under 35 U.S.C. §102(b) as being anticipated by Pernas et al. (PTO-892; Reference V). (Office action paragraph no. 10)

The rejection of claims 33, 35 and 36 is moot in view of the cancellation of these claims without prejudice or disclaimer. The rejection of claim 32 is overcome by the amendment to the claim.

The Examiner states that Pernas et al. teaches an allergen inactivating method for dust mite extract-Df allergens Der p 1 and Der f 1 (enzymes proteases) in SDS and EDTA (surfactant, salt). Applicant submits that Pernas et al. does not disclose the requirement of claim 32 for an enzyme "wherein the enzyme is an enzyme of *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene, or papain." Reconsideration of the rejection is respectfully requested.

Claims 35-36 are rejected under 35 U.S.C. §102(b) as being anticipated by Chen et al. (PTO-892; Reference W). (Office action paragraph no. 11)

The rejection of claims 35 and 36 is moot in view of the cancellation of these claims without prejudice or disclaimer.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,
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PATENT & TRADEMARK OFFICE

Enclosures: Document: "Mite Extract-Df"
Document "*Pfu* Protease S"

H:\040\040040\Amendment in re OA of 08-19-08

Pfu Protease S

Code No. 7339
Size: 500 U

Shipping at 4°C
Stored at 4°C

Lot No.
Conc.: 100 U/ml
Volume: 5 ml
Expiry Date:

Source: *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene.

Form: 25 mM Tris-HCl buffer, pH7.6 containing 40% ethanol

Storage: 4°C

Purity: Homogeneous in SDS-PAGE

Description: *Pfu* protease S is an endo-type Serine protease with broad specificity toward native and denatured proteins.

Activities: 9.5 U/mg (at 95°C)

Definition of Activity: One unit of enzyme activity corresponds to the amount required to hydrolyze 1 μmol of Suc-AAPF-pNA at 95°C, pH7.0 in one minute.
Suc-AAPF-pNA: N-succinyl Ala-Ala-Pro-Phe *p*-nitroanilide

Properties:
- Molecular weight: 42,906 (amino acid composition)
  45,000 (SDS-PAGE)
- Optimum temperature: 85-95°C
- Optimum pH: 6-8
- Thermal stability: retains 80% activity after 3 hrs at 95°C, pH7.0
- Torelance to denaturants:
  - 1% SDS; retains 50% activity after 24 hrs at 95°C, pH7.0
  - 6.4 M urea; retains 70% activity after 1 hr at 95°C, pH7.0
  - 50% acetonitrile; retains 90% activity after 1 hr at 95°C, pH7.0
- Inhibitor: PMSF

●由来 *Bacillus* species carrying a plasmid that encodes the *Pyrococcus furiosus* protease gene.

●形状 40%エタノールを含む25 mM Tris-HCl (pH7.6)溶液

●保存 4℃

●純度 SDS-PAGEにおいて単一

●反応
変性タンパク質、未変性タンパク質のペプチド結合を加水分解するエンド型セリンプロテアーゼ。基質特異性は広い。

●比活性 9.5 U/mg (95℃)

●活性の定義
Suc-AAPF-pNAを基質として、95℃、pH7.0で1分間に1 μmolのp-nitroanilineを生成する酵素活性を1Uとする。
Suc-AAPF-pNA :N-succinyl Ala-Ala-Pro-Phe *p*-nitroanilide

●一般的性質
- 分子量： 42,906（アミノ酸配列）
  45,000（SDS-PAGE）
- 至適温度：85℃～95℃
- 至適pH：6～8
- 熱安定性：95℃、pH7.0 3時間処理後に80%の活性を保持している。
- 変性剤耐性： 1%SDS；95℃、pH7.0、24時間処理後に50%の活性を保持している。
  6.4M尿素：95℃、pH7.0、1時間処理後に70%の活性を保持している。
  50%アセトニトリル；95℃、pH7.0、1時間処理後に90%の活性を保持している。
- 阻害剤：PMSF

Note
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COSMO BIO CO., LTD.
Inspiration for Life Science

Catalog No. LSL-LG-5339

Mite Extract-Df

1. Description

Freezed Dry powder (Mite-Df Crude Extract)

This product extracted from House Dust Mites, Dermatophagoides farinae (Hughes)*.

Protein : 10mg

Add 2.5ml of distilled water. It will become 5mM Borate buffered saline (pH8.0), 0.9% NaCl [BBS] solution.

* Mites were homogenized with 10-fold 50mM Phosphate buffer (pH7.2) in an ice bath, and the homogenate were stirred at 4℃ for 24 hours, and centrifuged at dialyzed 4 times by BBS.

2. Storage

Store below 4℃ (below -20℃ for prolonged storage).

For research use only; not for use as a diagnostic.

COSMO BIO CO., LTD.
Inspiration for Life Science

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